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CLERK U.S. DISTRICT COURT  
CENTRAL DIST. OF CALIF.  
LOS ANGELES

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Chief, Criminal Division  
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Attorney for Plaintiff  
UNITED STATES OF AMERICA

UNITED STATES DISTRICT COURT  
FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,  
Plaintiff,  
v.  
FASCIA BIOSYSTEMS LLC,  
Defendant.

CR No. 10

CR 10 00046

PLEA AGREEMENT FOR DEFENDANT  
FASCIA BIOSYSTEMS, LLC

1. This constitutes the plea agreement between Fascia Biosystems LLC ("defendant") and the United States Attorney's Office for the Central District of California ("the USAO") in the above-captioned case. This agreement is limited to the USAO and cannot bind any other federal, state or local prosecuting, administrative or regulatory authorities.

PLEA

2. Defendant gives up the right to trial, judgment, and sentencing before a district judge, and agrees to proceed before

1 a magistrate judge and to plead guilty to the sole count of the  
2 information attached to this agreement as Exhibit A or a  
3 substantially similar form.

4 NATURE OF THE OFFENSE

5 3. In order for defendant to be guilty of the sole count  
6 of the information, which charges a misdemeanor violation of  
7 Title 42, United States Code, Sections 264 and 271 and Title 21,  
8 Code of Federal Regulations, Sections 1271.21(a) and (c), which  
9 prohibit the failure to register and update certain information  
10 required to be maintained by establishments that manufacture,  
11 recover, process, store, label, package, or distribute human  
12 cells, tissues, and cellular and tissue-based products ("HCT/P"),  
13 the following must be true: (1) Defendant operated an  
14 establishment that manufactured HCT/P such that defendant was  
15 required to register and submit a list of HCT/P to the U.S. Food  
16 and Drug Administration ("FDA"), (2) defendant recovered,  
17 processed, stored, labelled, packaged, or distributed HCT/P after  
18 the submission of that list and which HCT/P did not appear on  
19 that list, and (3) defendant failed to submit to the FDA an  
20 update listing that included this post-submission HCT/P at the  
21 time of the change or by the subsequent June or December,  
22 whichever occurred first after the change. Defendant admits that  
23 defendant is, in fact, guilty of this offense as described in the  
24 information.

PENALTIES AND RESTITUTION

4. The statutory maximum sentence that the Court can impose on an organization for a violation of Title 42, United States Code, Sections 264 and 271 and Title 21, Code of Federal Regulations, Sections 1271.21(a) and (c) is: five years probation; a fine of \$200,000, or twice the gross gain or gross loss resulting from the offense, whichever is greatest; and a mandatory special assessment of \$125.

5. Defendant understands that the conviction in this case may subject defendant to various collateral consequences, including but not limited to suspension or revocation of a license. Defendant understands and agrees that unanticipated collateral consequences will not serve as grounds to withdraw defendant's guilty plea.

FACTUAL BASIS

6. Defendant and the USAO agree and stipulate to the statement of facts provided below. This statement of facts includes facts sufficient to support a plea of guilty to the charges described in this agreement. It is not meant to be a complete recitation of all facts relevant to the underlying criminal conduct or all facts known to defendant that relate to that conduct.

At all time relevant to the information, defendant Fascia Biosystems LLC was in the business of manufacturing human cells, tissues, and cellular and tissue-based products ("HCT/P"), specifically, the processing, storing, labelling, packaging, and

1 distributing of whole Achilles tendon that was ground to specific  
2 particle sizes and then filled into syringes and placed into  
3 heat-sealed foil pouches. Defendant marketed this HCT/P product,  
4 known as "Fascian," for the purpose of, for example, the  
5 implantation and injection in the treatment of wrinkles or acne  
6 scars, or the performance of lip augmentation or cellulite  
7 injection. Because it manufactured, recovered, processed,  
8 stored, labelled, packaged, or distributed HCT/P, defendant was  
9 required to register and submit a list of HCT/P to the FDA.  
10 After the submission of its initial HCT/P list to the FDA,  
11 defendant recovered, processed, stored, labelled, packaged, and  
12 distributed HCT/P on or about December 18, 2007, January 26,  
13 2008, April 11, 2008, and April 30, 2008 (the "2007/2008 HCT/P").  
14 Because the 2007/2008 HCT/P was initially recovered before May  
15 25, 2005, defendant's activities were subject to Title 21, Code  
16 of Federal Regulations, Section 1271.21. The 2007/2008 HCT/P did  
17 not appear on Defendant's initial list, so that Defendant was  
18 required to submit an updated HCT/P listing to reflect the  
19 2007/2008 HCT/P at the time of the change or by the subsequent  
20 June or December that occurred first after the change. Defendant  
21 failed to provide an updated HCT/P listing on those dates, as  
22 required by the Code of Federal Regulations.

23 WAIVER OF CONSTITUTIONAL RIGHTS

24 7. By pleading guilty, defendant gives up the following  
25 rights:

26 a) The right to persist in a plea of not guilty.  
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1           b) The right to a speedy and public trial by jury.

2           c) The right to be presumed innocent and to have the  
3 burden of proof placed on the government to prove defendant  
4 guilty beyond a reasonable doubt.

5           e) The right to confront and cross-examine witnesses  
6 against defendant.

7           f) The right to present evidence in opposition to the  
8 charges, including the right to call witnesses and to subpoena  
9 those witnesses to testify.

10          g) The right, if defendant chose not to present  
11 evidence, to have that choice not be used against defendant.

12          h) Any and all rights to pursue any affirmative  
13 defenses, Fourth Amendment or Fifth Amendment claims, and other  
14 pretrial motions that have been filed or could be filed.

15                               SENTENCING FACTORS

16          8. Defendant understands that the Court is required to  
17 consider and apply the United States Sentencing Guidelines  
18 ("U.S.S.G." or "Sentencing Guidelines") but may depart from those  
19 guidelines under some circumstances.

20          9. Defendant and the USAO agree that an appropriate  
21 disposition of this case is that the Court impose a sentence of:  
22 \$100,000 fine; payment of the costs of destroying the HCT/P  
23 seized by law enforcement in connection with this investigation,  
24 which amount will not exceed \$5,000; and a \$125 special  
25 assessment. Defendant and the USAO agree that, pursuant to  
26 Sentencing Guideline §§ 8D1.1 through 8D1.4, organization  
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1 probation is not warranted, because (i) defendant agrees to pay  
2 the entire \$100,000 fine and other costs and assessments by the  
3 time of sentencing; and (ii) Defendant and its affiliated  
4 entities have ceased engaging in the business of manufacturing,  
5 recovering, processing, storing, labelling, packaging, or  
6 distributing HCT/P.

7 10. The Court will determine the facts and calculations  
8 relevant to sentencing. Both defendant and the USAO are free to:  
9 (a) supplement the facts by supplying relevant information to the  
10 United States Probation Office and the Court, (b) correct any and  
11 all factual misstatements relating to the calculation of the  
12 sentence.

13 11. Defendant understands and agrees that this agreement is  
14 entered into pursuant to Federal Rule of Criminal Procedure  
15 11(c)(1)(C) and that, in the absence of a breach by Defendant of  
16 this agreement, either Defendant or the USAO may withdraw from  
17 this agreement and render it null and void if the Court refuses  
18 to be bound by this agreement.

19 DEFENDANT'S OBLIGATIONS

20 12. Defendant agrees to:

21 a) Plead guilty as set forth in this agreement to a  
22 one-count information in the form attached to this agreement as  
23 Exhibit A or a substantially similar form. Defendant enters into  
24 this agreement, and will enter its guilty plea before the Court,  
25 through an officer, agent, or attorney authorized to so act by a  
26 duly-enacted resolution of defendant, in the form attached hereto  
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1 as Exhibit B or a substantially similar form.

2 b) Not knowingly and willfully fail to abide by all  
3 sentencing stipulations contained in this agreement.

4 c) Not commit any crime.

5 d) Not knowingly and willfully fail to be truthful at  
6 all times with Pretrial Services, the U.S. Probation Office, and  
7 the Court.

8 e) Pay the fine of \$100,000 and special assessment at  
9 or before the time of sentencing, in the form of two cashier's  
10 checks made payable to the Clerk, United States District Court,  
11 one for the fine and the other for the special assessment.

12 THE USAO'S OBLIGATIONS

13 13. If defendant complies fully with all defendant's  
14 obligations under this agreement, the USAO agrees to abide by all  
15 sentencing stipulations contained in this agreement.

16 BREACH OF AGREEMENT

17 14. If defendant, at any time between the execution of this  
18 agreement and defendant's sentencing on a non-custodial sentence  
19 or surrender for service on a custodial sentence, knowingly  
20 violates or fails to perform any of defendant's obligations under  
21 this agreement ("a breach"), the USAO may declare this agreement  
22 breached. If the USAO declares this agreement breached, and the  
23 Court finds such a breach to have occurred, defendant will not be  
24 able to withdraw defendant's guilty plea, and the USAO will be  
25 relieved of all of its obligations under the agreement.

26 15. Following a knowing and willful breach of this  
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1 agreement by defendant, should the USAO elect to pursue any  
2 charge that was either dismissed or not filed as a result of this  
3 agreement, then:

4 a) Defendant agrees that the applicable statute of  
5 limitations is tolled between the date of defendant's signing of  
6 this agreement and the commencement of any such prosecution or  
7 action.

8 b) Defendant gives up all defenses based on the statute  
9 of limitations, any claim of preindictment delay, or any speedy  
10 trial claim with respect to any such prosecution, except to the  
11 extent that such defenses existed as of the date of defendant's  
12 signing of this agreement.

13 c) Defendant agrees that: (i) any statements made by  
14 defendant, under oath, at the guilty plea hearing; ii) the  
15 stipulated factual basis statement in this agreement; and iii)  
16 any evidence derived from such statements, are admissible against  
17 defendant in any future prosecution of defendant, and defendant  
18 shall assert no claim under the United States Constitution, any  
19 statute, Rule 410 of the Federal Rules of Evidence, Rule 11(f) of  
20 the Federal Rules of Criminal Procedure, or any other federal  
21 rule, that the statements or any evidence derived from any  
22 statements should be suppressed or are inadmissible.

23 LIMITED MUTUAL WAIVER OF APPEAL AND COLLATERAL ATTACK

24 16. Defendant gives up the right to appeal any sentence  
25 imposed by the Court and the manner in which the sentence is  
26 determined, provided that the sentence is that agreed to in  
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1 paragraph 9 above. Defendant also gives up any right to bring a  
2 post-conviction collateral attack on the conviction or sentence,  
3 except a post-conviction collateral attack based on a claim of  
4 ineffective assistance of counsel, a claim of newly discovered  
5 evidence, or a explicitly retroactive change in the applicable  
6 Sentencing Guidelines, sentencing statutes, or statutes of  
7 conviction.

8 17. The USAO gives up its right to appeal the Court's  
9 Sentencing Guidelines calculations, provided that the sentence is  
10 that agreed to in paragraph 9 above.

11 COURT NOT A PARTY

12 18. The Court is not a party to this agreement and need not  
13 accept the parties' stipulations or the sentence agreed to in  
14 paragraph 9 above. In the absence of a breach by Defendant of  
15 this agreement, however, either defendant or the USAO may  
16 withdraw from this agreement and render it null and void if the  
17 Court refuses to be bound by this agreement.

18 NO ADDITIONAL AGREEMENTS

19 19. Except as set forth herein, there are no promises,  
20 understandings or agreements between the USAO and defendant or  
21 defendant's counsel. Nor may any additional agreement,  
22 understanding or condition be entered into unless in a writing  
23 signed by all parties or on the record in court.

24 //

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PLEA AGREEMENT PART OF THE GUILTY PLEA HEARING


20. The parties agree and stipulate that this Agreement will be considered part of the record of defendant's guilty plea hearing as if the entire Agreement had been read into the record of the proceeding.

This agreement is effective upon signature by defendant and an Assistant United States Attorney.

AGREED AND ACCEPTED

UNITED STATES ATTORNEY'S OFFICE  
FOR THE CENTRAL DISTRICT OF CALIFORNIA

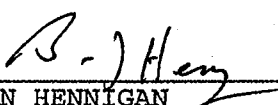
GEORGE S. CARDONA  
Acting United States Attorney

  
RONALD L. CHENG  
Assistant United States Attorney

JANUARY 15, 2010  
Date

In my capacity as outside counsel of defendant Fascia Biosystems LLC (the "Corporation"), I am authorized to enter into this plea agreement on behalf of the Corporation and bind the Corporation to it. I have obtained proper written authorization to do so from the Corporation, in the form of the corporate resolution attached as Exhibit B to this agreement. The Corporation has carefully reviewed every part of this agreement with the Corporation's outside counsel. I understand the terms of this agreement, and, on behalf of the Corporation, I voluntarily agree to them. Before signing this agreement, I consulted with the Corporation. I fully advised the Corporation of the Corporation's rights, of possible defenses, of the Sentencing Guidelines provisions, and of the consequences of

1 entering into this agreement. No other promises or inducements  
2 have been made to the Corporation or me, other than those  
3 contained in this agreement. Furthermore, no one has threatened  
4 or forced the Corporation or me, on the Corporation's behalf, in  
5 any way to enter into this agreement.

6  
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8 BRIAN HENNIGAN  
9 Outside Counsel for Defendant  
10 FASCIA BIOSYSTEMS LLC  
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1/14/10  
Date

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, ) CR 10-\_\_\_\_\_  
Plaintiff, )  
v. ) INFORMATION  
FASCIA BIOSYSTEMS LLC, ) [42 U.S.C. §§ 264, 271; 21  
Defendant. ) C.F.R. §§ 1271.21(a) and (c):  
Registration of human cells,  
tissues, and cellular and  
tissue-based products]  
[Class A Misdemeanor]

The United States Attorney charges:

[42 U.S.C. §§ 264, 271; 21 C.F.R. §§ 1271.21(a) and (c)]

On or about June 1, 2008, in Los Angeles County, within the Central District of California, defendant FASCIA BIOSYSTEMS LLC did not register and update its registration of human cells, tissues, and cellular and tissue-based products ("HCT/P"), that is, ground Achilles tendon marketed as "Fascian," as FASCIA BIOSYSTEMS LLC was required to perform pursuant to Title 21, Code of Federal Regulations, Sections 1271.21(a) and (c) for HCT/P

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WLH:RLC

EXHIBIT A

1 received and ground on December 18, 2007, January 26, 2008, April  
2 11, 2008, and April 30, 2008.

3  
4 GEORGE S. CARDONA  
5 Acting United States Attorney  
6

7 CHRISTINE C. EWELL  
8 Assistant United States Attorney  
9 Chief, Criminal Division

10 WESLEY L. HSU  
11 Assistant United States Attorney  
12 Chief, Cyber and Intellectual Property  
13 Crimes Section

14 MARK C. KRAUSE  
15 Assistant United States Attorney  
16 Deputy Chief, Cyber and Intellectual  
17 Property Crimes Section

18 RONALD L. CHENG  
19 Assistant United States Attorney  
20 Cyber and Intellectual Property Crimes  
21 Section  
22  
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**EXHIBIT B TO PLEA AGREEMENT OF FASCIA BIOSYSTEMS LLC**

**RESOLUTION OF FASCIA BIOSYSTEMS LLC**

On \_\_\_\_\_, 2009, Fascia Biosystems LLC (the "Corporation") resolved as follows:

**WHEREAS**, the Corporation has been engaged in discussions with the United States Attorney's Office for the Central District of California (the "Office") regarding certain issues arising out of, in connection with, the manufacturing, processing, storing, labelling, packaging, and distributing of human cells, tissues, and cellular and tissue-based products;

**WHEREAS**, in order to resolve such discussions, it is proposed that the Corporation enter into a certain plea agreement with the Office;

**WHEREAS**, the Corporation's Outside Counsel ("Outside Counsel") has advised the Corporation of the Corporation's rights, possible defenses, and the consequences of entering into such an agreement with the Office; and

**WHEREAS**, the Corporation is satisfied with the representation of counsel which the Corporation received in this matter.

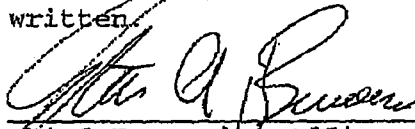
The Corporation hereby **RESOLVES** that:

1. the Corporation consents to the filing in the United States District Court for the Central District of California of an Information charging the Corporation with one count of violating Title 42, United States Code, Sections 264 and 271 and Title 21, Code of Federal Regulations, Sections 1271.21(a) and (c), for the failure to register and update certain information required to be maintained by establishments that manufacture, recover, process, store, label, package, or distribute human cells, tissues, and cellular and tissue-based products ("HCT/P").
2. the Corporation agrees to pay a fine of \$100,000, the costs of destroying the HCT/P seized by law enforcement in connection with this investigation, which amount will not exceed \$5,000, and a \$125 special assessment in connection with the plea agreement described in paragraph 3 below and to execute the ongoing obligations described therein;

**EXHIBIT** B

3. Outside Counsel, or his delegate, hereby is authorized on behalf of the Corporation to execute the plea agreement substantially in such form as reviewed by the Corporation with Outside Counsel on December 7, 2009, with such changes as the Outside Counsel, or his delegate, may approve;
4. the Outside Counsel, or his delegate, hereby is authorized to appear before the United States District Court for the Central District of California and enter a guilty plea on behalf of the Corporation to the Information;
5. the Corporation hereby authorizes, empowers and directs the Outside Counsel, or his delegate, to take any and all actions as may be necessary or appropriate, and to approve and execute the forms, terms or provisions of any agreement or other documents as may be necessary or appropriate to carry out and effectuate the purpose and intent of the foregoing resolutions; and
5. All of the actions of the Outside Counsel, which actions would have been authorized by the foregoing resolutions except that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved and adopted as actions on behalf of the Corporation.

IN WITNESS WHEREOF, the Corporation has executed this Resolution effective as of the day and year first above written.

  
 Chief Executive Officer  
 Fascia Biosystems LLC

CERTIFICATE OF SERVICE

I, **SUSAN M. CRUZ**, declare:

That I am a citizen of the United States and resident or employed in Los Angeles County, California; that my business address is the Office of United States Attorney, United States Courthouse, 312 North Spring Street, Los Angeles, California 90012; that I am over the age of eighteen years, and am not a party to the above-entitled action;

That I am employed by the United States Attorney for the Central District of California who is a member of the Bar of the United States District Court for the Central District of California, at whose direction I served a copy of: **PLEA AGREEMENT FOR DEFENDANT FASCIA BIOSYSTEMS, LLC**

**service was:**

☒ Placed in a closed envelope, for collection and interoffice delivery addressed as follows:

☐ Placed in a sealed envelope for collection and mailing via United States Mail, addressed as follows:

☐ By hand delivery addressed as follows:

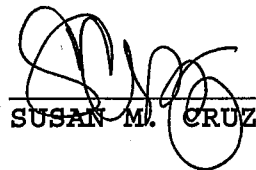
☐ By facsimile as follows:

☐ By messenger as follows: ☐ By federal express as follows:

**IRELL & MANELLA LLP  
BRIAN J. HENNIGAN, ESQ.  
1800 AVENUE OF THE STARS, SUITE 900  
LOS ANGELES, CA 90067-4276  
TEL: (310) 277-1010  
FAX: (310) 203-7199**

This Certificate is executed on **January 19, 2010**, at Los Angeles, California.

I certify under penalty of perjury that the foregoing is true and correct.

  
\_\_\_\_\_  
**SUSAN M. CRUZ**